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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,964	11/05/2001	Carlos Miguel Carcagno	1909.0030002	5291

7590 02/24/2005

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EXAMINER	
TATE, CHRISTOPHER ROBIN	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 02/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/830,964	CARCAGNO ET AL.	
	Examiner	Art Unit	
	Christopher R. Tate	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-16* is/are rejected.

7)☒ Claim(s) *2* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment and Declaration filed December 1, 2004 are acknowledged and have been entered. Claims 1-16 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1 and 3-12 stand rejected under 35 U.S.C. 112, first paragraph for the reasons set forth in the previous Office action (with respect to the order of steps) which are restated below.

The specification, while being enabling for a method of purifying recombinant human erythropoietin (EPO) from cell culture supernatants via employing the order of process steps recited in claim 2, does not reasonably provide enablement for purifying human recombinant EPO from any and all cell culture supernatants via any order of the combination of numerous recited process steps instantly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims (for the reasons set forth in the previous Office action).

Applicants' arguments, including those presented within the Declaration filed December 1, 2004, have been carefully considered but are not deemed to be persuasive of error in the above rejection. Applicants argue that the December 1, 2004 Declaration of Dr. Marcelo E. Criscuolo describes an additional experiment showing that the purification of human EPO may be performed using a protocol comprising the steps as described in the specification, wherein the purification steps are performed in variable order. However, the steps shown within the experiment set forth in the December 1, 2004 Declaration do not share numerous working

parameters with the instantly disclosed process step working parameters - see, e.g., the differences in working parameters for the hydrophobic interaction chromatography, anionic exchange chromatography, and cationic exchange chromatography with respect to column diameter, bed height, and volume (including the use of a pre-column within the experiment set forth in the 12/1/04 Declaration), as well as the conductivity requirements for the hydrophobic exchange chromatography and cationic exchange chromatography, between those shown in the December 1, 2004 Declaration and those instantly disclosed on pages 12-14 of the instant specification (to name a few). Please also note that the instantly claimed process steps are deplete of any of the complex and detailed working conditions required within each step of the instantly disclosed purification processes. It should also be noted that it would not make scientific sense to use various permutations in the order of the recited steps – e.g. (to name one of many examples), it would not make scientific sense to perform the step "concentration and diafiltration" followed by "concentration and diafiltration". Further, it is well accepted in the protein purification art that such purification steps including the actual detailed working conditions required by each step, has a profound impact on the final purified protein product.

Accordingly, since the instant specification only demonstrates the step-by-step purification of human recombinant EPO via the essential order recited in claim 2 (including the detailed working parameters required for each of these steps - in the order defined by claim 2), one of skill in the art would not reasonably be able to successfully purify human recombinant EPO from cell culture media (containing human recombinant EPO therein) via any and all orders of the recited claim steps without undue experimentation other than using the particular order of steps defined by claim 2 (with the guidance provided by the demonstrated order of process steps

– including the detailed working conditions of each step, as instantly disclosed) and clearly not in via any and all orders of the numerous steps instantly recited.

Claim Rejections - 35 USC § 102

Claims 13-16 stand rejected under 35 U.S.C. 102(b) as being anticipated by Rosen (WO 92/06116) for the reasons set forth in the previous Office action.

Applicants' arguments have been carefully considered but are not deemed to be persuasive of error in the rejection. Applicants argue that Rosen does not describe a substantially pure EPO prepared by the claimed method. However, it is reemphasized that "the patentability of a product does not depend upon its method of production. If the product in [a] product-by-process claim is the same as or obvious from a product of the prior art, [then] the claim is unpatentable even though the prior [art] product was made by a different process." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985); In re Marosi, 218 USPQ 289, 292 (Fed. Cir. 1983). Accordingly, the method by which the substantially pure human recombinant EPO taught by Rosen is obtained is not deemed to lend patentable distinction to the substantially pure human recombinant EPO taught thereby. Applicants further argue that Rosen does not teach the same EPO protein sequence as there is an additional amino acid at position 166 and that, in contrast, the present invention relates to an EPO molecule with 165 amino acids – and, therefore, the Examiner's statement that the patentability of a product does not depend upon its method of production is only sound if the products are identical. However, the instantly disclosed sequence of SEQ ID NO. 3 is identical to that taught by Rosen with respect to amino acids 1-165 (which is the sequence of instant SEQ ID NO. 3). Accordingly, the EPO taught by Rosen does, in fact, comprise the protein sequence of SEQ ID NO. 3. Applicants further argue that the purification

of a glycoprotein may result in different preparations which can be influenced by the selectivity of the procedural steps employed by its purification (please note that this argument supports the reasoning discussed in the USC 112, first paragraph non-enablement rejection above). However, in terms of isolating/purifying a particular EPO from a particular EPO producing cell line culture, that particular EPO would ultimately be what is isolated/purified therefrom (e.g., as readily admitted by Applicants, a preferred human recombinant EPO are preferably obtained from EPO producing recombinant cells as disclosed in US 4,703,008 by Lin – see, e.g., page 7, lines 12-19, of the instant specification). Further, this argument is irrelevant to the above art rejection over the substantially pure human recombinant EPO taught by Rosen.

[It should be noted that, although no other art rejections have been made over the substantially pure EPO product of claims 13-16, various other prior art references are available (e.g., the X references cited in corresponding PCT/US99/26241 of record) which also appear to read upon these claims. Accordingly, to hasten prosecution, it is strongly suggested that claims 13-16 be canceled in response to this Office action.]

Allowable Subject Matter

As set forth in the previous Office action, Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

No claim is allowed.

The examiner assigned to this Application has changed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher R. Tate
Primary Examiner
Art Unit 1654